(15)

subcutaneously in the neck, in the presence of QS-21 (purified fraction of saponin extracted from *Quillarja Saponaria Molina*), and the mice that received urease plus LT orally exhibited a 10- to 100-fold decrease in the infection when compared with the unimmunized mice. The BAY R1005 (N-(2-deoxy-2-L-leucylarnino-beta-D-glucopyranosyl)-N-octa-decyldodecanoylamide acetate) adjuvant induced an identical decrease, which was more pronounced in the mice immunized in the lumbar region.

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Subject

In contrast to the monkeys receiving the mucosal prime/parenteral boost regimen, monkeys immunized by the parenteral route with urease + BAY R1005 (N-(2-deoxy-2-L-leucylamino-beta-D-glucopyranosyl)-N-octa-decyldodecanoylamide acetate) showed no difference in *H. pylori* colonization compared with the sham-immunized controls (p = 1.00), while monkeys treated with urease + alum showed a partial effect (p=0.33) (Figure 8). Culture data was unavailable for one of the monkeys in the group receiving urease + BAY R1005 (N-(2-deoxy-2-L-leucylamino-beta-D-glucopyranosyl)-N-octa-decyldodecanoylamide acetate), due to heavy contamination of gastric samples with other bacteria.

In the Claims:

Please cancel claims 10, 12, 16, 17, and 41, without prejudice, and amend claims 5, 7-9, 25, 37, 38, 45, and 46 to read as follows.

5. (Twice Amended) A method of inducing a prophylactically effective immune response against Helicobacter in a mammal, said method consisting essentially of administering to said mammal a prophylactically effective amount of a prophylactically effective *Helicobacter pylori* polypeptide antigen by the subdiaphragmatic, systemic route.

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7. (Amended three times) The method of Claim 6, further comprising induction of a Th2type immune response, wherein the immune response of said mammal is characterized by either

- (i) a ratio of the ELISA IgG2a:IgG1 titers greater than or equal to 1:100, or (ii) a ratio of the ELISA IgG2a:IgA titers greater than or equal to 1:100.
- 8. (Twice Amended) The method of Claim 7, in which the immune response of said mammal is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers greater than or equal to 1:10, or (ii) by a ratio of the ELISA IgG2a:IgA titers greater than or equal to 1:10.
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- 9. (Twice Amended) The method of Claim 8, in which the immune response of said mammal is characterized either (i) by a ratio of the ELISA IgG2a:IgG1 titers greater than or equal to 1:2, or (ii) by a ratio of the ELISA IgG2a:IgA titers greater than or equal to 1:2.
- 25. (Twice Amended) A method of inducing a prophylactically effective immune response against Helicobacter infection in a mammal, said method comprising in order the steps of:

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mucosally administering a prophylactically effective amount of a prophylactically effective *Helicobacter pylori* antigen to said mammal; and then

parenterally administering a prophylactically effective amount of a prophylactically effective *Helicobacter pylori* antigen to said mammal.

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37. (Amended) The method of claim 25, further comprising carrying out more than one mucosal administration.

- 38. (Amended) The method of claim 25, further comprising carrying out more than one parenteral administration.
- 45. (Amended) The method of Claim 25, further comprising mucosally co-administering a mucosal adjuvant selected from the group consisting of *Escherichia coli* heat labile enterotoxin (LT), cholera toxin (CT), *Clostridium difficile* toxin, *Pertussis* toxin (PT), and combinations, subunits, toxoids, and mutants derived therefrom with the mucosally administered *Helicobacter pylori* antigen.

46. (Amended) The method of Claim 25, in which a parenteral adjuvant selected from the group consisting of alum, QS-21 (purified fraction of saponin extracted from *Quillarja Saponaria Molina*), DC-CHOL (3-beta-(N-(N',N'-dimethylamino-ethane)carbamoyl)cholesterol), and BAY R1005 (N-(2-deoxy-2-L-leucylamino-beta-D-glucopyranosyl)-N-octa-decyldodecanoylamide acetate) is co-administered with the parenterally administered *Helicobacter pylori* antigen.